

REMARKS

Reconsideration and allowance of this application are respectfully requested in light of the following remarks.

Claim Status

Claims 1–20 were presented in the originally filed application. Claims 14–20 are withdrawn. Claims 1 and 13 are amended. Claims 3, 7, 11 and 12 are cancelled. Claims 1, 2, 4–6, 8 and 13 are pending. No new matter was added.

Discussion

Claims 1, 2, 4–6 and 8–13 stand rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant traverses.

Applicant has followed the Examiner's suggestion and amended the language of independent claims 1 and 13 to read, "wherein the pH value of the fermentation medium is set prior to the start of the fermentation in the range of..." in order to clarify the language of the claims. In light of this amendment, Applicant respectfully requests that the rejection be removed and the claims allowed. Regarding dependent claims 2, 4–6 and 8–12, these claims no longer depend from rejected claims and should also be allowed.

Claims 1, 2, 4-6 and 8-13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,582,941 (Yokochi), U.S. Patent No. 6,509,178 (Tanaka), EP 0 113 183 (Carson), and Bajpai. Applicant traverses.

As stated in Applicant's previous response, it appears from the Examiner's comments that the novelty of the instant invention is not in question. The Examiner does however continue question the inventive step of this instant invention. In order to defeat the Examiner's rejection, Applicant has further clarified the instant invention by amending independent claims 1 and 13 to apply only to either *Ulkenia sp.* SAM 2179 or *Schizochytrium sp.* SR 21 in addition to revising the content of CaCO₃ in the fermentation medium to 7.5 g/l ± 0.5 g/l. Support for these amendments comes from claims 11 and 12 and Examples 3 and 4 in the instant specification. The isolation of PUFA's from the microorganisms *Ulkenia sp.* SAM 2179 or *Schizochytrium sp.* SR 21 in addition to the alteration to the fermentation medium overcomes the Examiner's rejection above.

The amendment of claims 1 and 13 clearly differentiate from Carson as Carson merely describes the use of CaCO₃ in an amount in the range of 0.5 to 5.0 g/l as pointed out by the Examiner in the final paragraph on page 4 carrying over to page 5 in the current office action.

Newly amended claims 1 and 13 now clearly demonstrate that the combination of Yokochi, Tanaka, Carson, and Bajpai fail to establish a prima facie case of

obviousness. MPEP §2143 "Basic Requirements of a *Prima Facie* Case of

Obviousness" states:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine references teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all claim limitations.

Regarding the third criterion, the court has stated that "to establish *prima facie* obviousness of a claimed invention, **all** the claim limitations must be taught or suggested by the prior art." *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

Applicant contends that none of the prior art references, Yokochi, Tanaka, Carson, and Bajpai, alone or in combination, teach, suggest, or provide a motivation for making an article of manufacture with all of the claim elements from independent claims 1 and 13. More specifically, Applicant contends that none of the prior art references, alone or in combination, teach, suggest or provide a motivation for a method for cultivating microorganisms of the order *Thraustochytriales*, comprising the steps of: cultivating microorganisms selected from the group comprising *Ulkenia* sp. SAM 2179 or *Schizochytrium* sp. SR 21 in a fermentation medium containing CaCO₃ as an essential means for pH value stabilization, where content of CaCO₃, in said fermentation medium is 7.5 g/l ± 0.5 g/l; wherein the pH value of the fermentation medium is set prior to the start of the fermentation in the range of 5 to 7 by adding a corresponding acid or base; followed by isolating PUFAs from the microorganisms

and/or the fermentation medium wherein the microorganisms bring forth a production of more than 10 wt% docosahexaenoic acid (DHA) per unit of weight of dry biomass.

The deficiencies of Tanaka, Yokochi, Carson and Bajpai were thoroughly discussed in previous office actions which is herein incorporated by reference. In summary, Bajpai clearly teaches that the pH value does not have to be kept within a range of 5-7, but instead is permitted to decrease far below pH 6 during cultivation. Consequently, Bajpai et al does not suggest or even hint at the cultivation of *Thraustochytriales* in the presence of $7.5 \text{ g/l} \pm 0.5 \text{ g/l}$ calcium carbonate as the essential means for pH value stabilization followed by isolating PUFAs from the microorganisms and/or the fermentation medium wherein the microorganisms bring forth a production of more than 10 wt% docosahexaenoic acid (DHA) per unit of weight of dry biomass. Additionally in Table 1, Bajpai clearly discloses very low DHA space-time yields. (DHA in biomass / biomass * 24 h/d/40h << 0.050mg/L. These low DHA space-time yields make it patently obvious that a person skilled in the art would never consider this document in order to solve the underlying problem solved by the instant invention.

As stated in the previous office action, the prior art reference or combination of references relied upon by the Examiner must teach or suggest all of the limitations of the claims. See *In re Zurko*, 111 F.3d 887, 888-89, 42 U.S.P.Q.2d 1467, 1478 (Fed. Cir. 1997); *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970) (“All words in a claim must be considered in judging the patentability of that claim against the prior art.”). The teachings or suggestions, as well as the expectation of

success, must come from the prior art, not applicant's disclosure. See *In re Vaeck*, 947 F.2d 488, 493, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). In this instance, from the information detailed above, it is clear that Yokochi, Tanaka, Carson and Bajpai fail to teach or suggest all the limitations of Applicant's claims.

Hindsight reconstruction is not permitted as the Federal Circuit has repeatedly warned that the requisite motivation to modify a reference must come from the prior art, not Applicant's specification. See *In re Dow Chem. Co.*, 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531-32 (Fed. Cir. 1988) ("there must be a reason or suggestion in the art for selecting the procedure used, other than the knowledge learned from the applicant's disclosure.") Using an Applicant's disclosure as a blueprint to reconstruct the claimed invention from isolated piece of the prior art contravenes the statutory mandate of section 103 of judging obviousness at the point in time when the invention was made. See *Grain Processing Corp. v. American Maize-Props. Co.*, 840 F.2d 902, 907, 5 U.S.P.Q.2d 1788, 1792 (Fed. Cir. 1988).

Only hindsight reconstruction based upon the instant specification would lead the Examiner to the conclusion that the claims in the instant application are rejected under §103 as unpatentable over Yokochi, Tanaka, Carson and Bajpai. Accordingly, the instant rejection of independent claims 1 and 13 must be removed.

In reference to claims 2, 4-6 and 8-10, dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious.

Hartness Int'l, Inc. v. Simplimatic Eng'g Co., 819 F.2d 1100, 1108, 2 USPQ2d 1826, 1831 (Fed. Cir. 1987); *In re Abele*, 684 F.2d 902, 910, 214 USPQ 682, 689 (CCPA 1982); see also *In re Sernaker*, 702 F.2d 989, 991, 217 USPQ 1, 3 (Fed. Cir. 1983). Thus, claims 2, 4-6 and 8-10 are not unpatentable over Yokochi, Tanaka, Carson and Bajpai and should be allowed.

Conclusion

Reconsideration and allowance of this application is respectfully requested in light of the previous amendment and comments.

Respectfully submitted,



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